Louis J. Lavigne, Jr. was appointed Executive Vice President of Genentech in March 1997 and Chief Financial Officer in August 1988. He previously served as Senior Vice President from July 1994 to March 1997 and as Vice President from July 1986 to July 1994. Mr. Lavigne joined Genentech in July 1982 from Pennwalt Corporation and became Controller in May 1983 and an officer of Genentech in February 1984.

Myrtle S. Potter was appointed Executive Vice President, Commercial Operations and Chief Operating Officer in May 2000. Prior to joining Genentech, she held the positions of President of U.S. Cardiovascular/Metabolics from November 1998 to May 2000, Senior Vice President of Sales, U.S. Cardiovascular/Metabolics from March 1998 to October 1998, Group Vice President of Worldwide Medicines Group from February 1997 to February 1998 and Vice President of Strategy and Economics, U.S. Pharmaceutical Group from April 1996 to January 1997 at Bristol-Myers Squibb. Previously, she held the position of Vice President of the Northeast Region Business Group at Merck & Co., Inc. from October 1993 to March 1996.

Richard H. Scheller, Ph.D. was appointed Executive Vice President, Research in September 2003. Previously, he served as Senior Vice President, Research from March 2001 to September 2003. Prior to joining Genentech, he served as Professor of Molecular and Cellular Physiology and of Biological Sciences at Stanford University Medical Center from September 1982 to February 2001 and as an investigator at the Howard Hughes Medical Institute from September 1990 to February 2001. He received his first academic appointment to Stanford University in 1982. He was appointed to the esteemed position of professor of Molecular and Cellular Physiology in 1993 and as an investigator in the Howard Hughes Medical Institute in 1994.

David A. Ebersman was appointed Senior Vice President, Product Operations in May 2001. He joined Genentech in February 1994 as a Business Development Analyst and subsequently served as Manager, Business Development from February 1995 to February 1996, Director, Business Development from February 1996 to March 1998, Senior Director, Product Development from March 1998 to February 1999 and Vice President, Product Development from February 1999 to May 2001. Prior to joining Genentech, he held the position of Research Analyst at Oppenheimer & Company, Inc.

Robert L. Garnick, Ph.D. was appointed Senior Vice President, Regulatory, Quality and Compliance in February 2001. Previously, he served as Vice President, Regulatory Affairs from February 1998 to February 2001, Vice President, Quality from April 1994 to February 1998, Senior Director, Quality Control from 1990 to 1994 and Director, Quality Control from 1988 to 1990. He joined Genentech in August 1984 from Armour Pharmaceutical, where he held various positions.

John M. Whiting was appointed Vice President in January 2001 and Controller and Chief Accounting Officer in October 1997. He previously served as Director, Financial Planning and Analysis from January 1997 to October 1997 and as Director, Operations, Financial Planning and Analysis from December 1996 to January 1997. He also served in a variety of financial positions at Genentech from 1989 to 1996. Prior to joining Genentech, he served as Senior Audit Manager at Arthur Young.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

See the footnotes labeled "Redemption of Our Special Common Stock," "Relationship With Roche" and "Capital Stock" in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

Stock Trading Symbol: **DNA**

Stock Exchange Listing

Our Common Stock trades on the New York Stock Exchange under the symbol "DNA." No dividends have been paid on the Common Stock. We currently intend to retain all future income for use in the operation of our business and for future stock repurchases and, therefore, do not anticipate paying any cash dividends in the foreseeable future.

Common Stockholders

As of December 31, 2003, there were approximately 1,921 stockholders of record of our Common Stock, one of which is Cede & Co., a nominee for Depository Trust Company (or DTC). All of the shares of Common Stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder.

Stock Prices

	Common Stock			
	2003		2002	
	High	Low	High	Low
4th Quarter	$95.35	$76.29	$36.85	$29.50
3rd Quarter	88.00	70.30	37.49	25.10
2nd Quarter	77.50	33.80	52.44	30.02
1st Quarter	39.75	31.53	55.15	45.72

Stock Repurchases

See the "Capital Stock" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for information on our stock repurchases.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial information has been derived from the audited consolidated financial statements. The information below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-K and the consolidated financial statements and related notes thereto included in Item 8 of this Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

SELECTED CONSOLIDATED FINANCIAL DATA

(in millions, except per share amounts)

	2003	2002	2001	2000	1999	
					New Basis (June 30 to December 31)[9]	Old Basis (January 1 to June 30)[9]
Total operating revenues[1]	$3,300.2	$2,583.7	$2,044.1	$1,514.2	$ 653.6	$638.6
Product sales	2,621.4	2,163.6	1,742.9	1,278.3	535.7	503.4
Royalties	500.9	365.6	264.5	207.3	96.7	92.6
Contract revenue	177.9	54.5	36.7	28.6	21.2	42.6
Income before cumulative effect of accounting changes	$ 610.1	$ 63.8	$ 155.9	$ (16.4)	$(1,245.1)	$ 87.6
Cumulative effect of accounting changes, net of tax	(47.6)[3]	—	(5.6)[6]	(57.8)[8]	—	—
Net income (loss)[2]	$ 562.5[3]	$ 63.8[5]	$ 150.3[6]	$ (74.2)[8]	$(1,245.1)[10]	$ 87.6[12]
Basic earnings (loss) per share	$ 1.09	$ 0.12	$ 0.29	$ (0.14)	$ (2.43)	$ 0.17
Diluted earnings (loss) per share	1.06	0.12	0.28	(0.14)	(2.43)	0.16
Total assets	$8,736.2[4]	$6,758.1	$7,146.9	$6,728.4	$ 6,549.8	—
Long-term debt	412.3[4]	— [7]	— [7]	149.7	149.7	—
Stockholders' equity	6,520.3	5,338.9	5,919.8	5,674.2	5,269.8[11]	—

We have paid no dividends.

All per share amounts reflect two-for-one stock splits that were effected in 2000 and 1999.

(1) Effective January 1, 2003, we made certain classification changes to our consolidated statements of income. Comparable amounts in prior years have been reclassified to conform to the 2003 presentation. For more information on our classification changes, see the "Description of Business and Summary of Significant Accounting Policies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

(2) Net income (loss) includes recurring charges of $154.3 million in 2003, $155.7 million in 2002, $321.8 million in 2001 and $375.3 million in 2000 related to the June 30, 1999 redemption of our special common stock (or the Redemption). See Note (10) below for the redemption charges in 1999.

(3) Net income in 2003 includes litigation settlements with Amgen, Inc. and Bayer, net of accrued interest and bond costs related to the City of Hope litigation judgment. Net income in 2003 also reflects our adoption of the Financial Accounting Standards Board Interpretation No. 46 (or FIN 46), "Consolidation of Variable Interest Entities," on July 1, 2003, which resulted in a $47.6 million charge, net of $31.8 million in taxes, (or $0.09 per share) as a cumulative effect of an accounting change in 2003.

(4) Upon adoption of FIN 46, we consolidated the entity from which we lease our manufacturing facility located in Vacaville, California. Accordingly, we have included $348.4 million of assets in property, plant and equipment at December 31, 2003. We also consolidated the entity's debt of $412.3 million and noncontrolling interests of $12.7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, at December 31, 2003.

(5) Net income in 2002 includes $543.9 million of litigation-related special charges, which are comprised of the City of Hope litigation judgment in the second quarter of 2002, and accrued interest and bond costs, and certain other litigation-related matters. Net income in 2002 also reflects our adoption of Statement of Financial Accounting Standards (or FAS) 141 and 142 on January 1, 2002. As a result of our adoption, reported net income increased by approximately $157.6 million (or $0.30 per share) due to the cessation of goodwill amortization and the amortization of our trained and assembled workforce intangible asset.

(6) Net income in 2001 reflects a $5.6 million charge (net of $3.8 million in taxes) as a cumulative effect of a change in accounting principle and changes in fair value of certain derivatives ($10.0 million gain) recorded in "other income, net" as a result of our adoption of FAS 133 on January 1, 2001.

(7) The $149.7 million of convertible subordinated debentures was reclassified to current liabilities in 2001 to reflect the March 27, 2002 maturity. We redeemed the debentures in cash at maturity.

(8) Net loss in 2000 includes costs of $92.8 million related to the sale of inventory that was written up at the Redemption and a $57.8 million (net of $38.5 million in taxes) cumulative effect of a change in accounting principle as a result of our adoption of Securities and Exchange Commission's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" on January 1, 2000.

(9) The June 30, 1999 Redemption created our New Basis of accounting. The Redemption was effective as of June 30, 1999; however, the transaction was reflected as of the end of the day on June 30, 1999 in the financial statements. As such, a vertical black line is inserted to separate the "Old Basis" and "New Basis" presentation. Accordingly, the Old Basis reflects the period January 1 through June 30, 1999, and all periods prior to the Redemption, and the New Basis reflects the period from June 30 through December 31, 1999, and all subsequent periods.

(10) Net loss for the period from June 30, 1999 to December 1999, New Basis, includes all amounts related to the Redemption of our Special Common Stock transaction. The net loss includes charges of $1,207.7 million related to the Redemption, legal settlements of $180.0 million, recurring charges of $197.7 million related to the Redemption and costs of $93.4 million related to the sale of inventory that was written up at the Redemption.

(11) Reflects the impact of the Redemption and related push-down accounting of $5,201.9 million of excess purchase price over net book value, net of charges and accumulated amortization of goodwill and other intangible assets at December 31, 1999.

(12) Net income for the period from January 1, 1999 to June 30, 1999, Old Basis, includes charges of $50.0 million related to legal settlements.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

In 2003, we delivered strong top-line and bottom-line growth. Operating revenues for 2003 increased 28 percent to more than $3 billion. Diluted earnings per share for 2003 increased to $1.06 per share compared to 12 cents per share for 2002, and net income for 2003 increased to $562.5 million compared to $63.8 million for 2002. Our financial position remains strong, with approximately $2.9 billion in unrestricted cash and marketable securities.

Key commercial successes in 2003 include total product sales of $2.6 billion, a 21 percent increase over 2002. Our marketed products continue to drive performance, with every product reporting growth in 2003. Total oncology sales increased 24 percent over 2002 and now constitute 73 percent of total product sales. In addition, 2003 included the approval and launch of two new products for immunological diseases, Xolair® (Omalizumab) for persistent asthma and Raptiva™ (efalizumab) for chronic plaque psoriasis. We launched Xolair in July 2003 and Raptiva in November 2003.

On our product development efforts, after receiving positive results from the pivotal trial of Avastin™ (bevacizumab) in first-line metastatic colorectal cancer, we filed the Biologics License Application (BLA) and received priority review status from the U.S. Food and Drug Administration (FDA). In early 2004, we received FDA approval for Avastin for use in combination with intravenous 5-fluorourcil-based chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum. Avastin is the first FDA-approved therapy designed to inhibit angiogenesis, the process by which new blood vessels develop, which is necessary to support tumor growth and metastasis. Finally, we filed a supplemental New Drug Application (sNDA) for the additional indication of Nutropin® [somatropin (rDNA origin) for injection]/ Nutropin AQ® [somatropin (rDNA origin) injection] for the long-term treatment of idiopathic short stature.

Our development pipeline has over 20 projects in various stages. In 2003, we and our collaborators began enrollment in multiple clinical trials, including Rituxan® (Rituximab) for rheumatoid arthritis, Lucentis™ (ranibizumab) for age-related macular degeneration, Avastin and Omnitarg™ (pertuzumab) in multiple tumor types, and Raptiva for psoriatic arthritis. We also entered more than 10 new projects into our development portfolio, including two new molecular entities: the fully humanized anti-CD20 antibody, which we will jointly develop with Biogen Idec and F. Hoffmann-La Roche Ltd (or Hoffmann-La Roche), an affiliate of Roche, and PRO1762 (formerly Apo2L/TRAIL), which we will jointly develop with Immunex, a subsidiary of Amgen, Inc.

We also finalized several business development agreements in 2003, including agreements with: Novartis Ophthalmics for ex-North American marketing of Lucentis for age-related macular degeneration; Biogen Idec Inc. for the development of one or more new humanized anti-CD20 antibodies for a broad range of diseases; Biogen (now Biogen Idec) for research and development of a BR3 modulator; Curis for a molecule in the hedgehog signaling pathway; and Lonza Group Ltd. for third-party manufacturing of Rituxan.

On the operations front, both our South San Francisco and Vacaville facilities have ramped up manufacturing efforts in order to meet the increased product demand. As mentioned above, we entered into a long-term manufacturing agreement with Lonza Biologics, under which Lonza will manufacture commercial quantities of Rituxan at Lonza's production facility in Portsmouth, New Hampshire. Finally, we made progress on our facility in Porriño, Spain (Genentech España) and now expect to bring it online in 2004 to produce Avastin for clinical trials. Both projects are important to have sufficient capacity to meet expected demand for our products.

In terms of our ongoing research projects, we continue our work in oncology, including our Tumor Antigen Program and mechanism of action studies. Angiogenesis also remains an important and broad arena of study for us, not only in oncology but also in vascular biology. Immunology is a growing area of expertise and emphasis for Genentech, and we are exploring several promising areas of research, including TNF (tumor necrosis factor) super family members, autoimmunity, transplant issues and allergy/asthma. Finally, we are developing a focus on

diagnostics for our novel, targeted treatments in order to strive to increase development success rates in our clinical trials and deliver the right drugs to the right patients.

In 2003, we were involved in challenges over contracts and intellectual property. We were able to resolve or make substantial progress in resolving several major contract differences through confidential negotiations. We settled our patent litigation with Amgen, resulting in a one-time payment to Genentech, increasing earnings per diluted share for 2003 by approximately $0.19. We also settled our litigation with Bayer for a one-time payment from that company. On February 25, 2004, Genentech, Novartis Pharma AG and Tanox, Inc. agreed that they have settled all litigation among them and finalized the detailed terms of their three-party collaboration.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our consolidated financial statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

Legal Contingencies

We are currently involved in certain legal proceedings as discussed in the "Leases Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K. We assess the likelihood of any adverse judgments or outcomes to these legal matters as well as potential ranges of probable losses. As of December 31, 2003, we have accrued $608.3 million, which represents our estimate of the costs for the current resolution of these matters. We developed these estimates in consultation with outside counsel handling our defense in these matters using the facts and circumstances known to us at that time. The nature of these matters is highly uncertain and subject to change, as a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the outcome of these matters. An outcome of such matters different than previously estimated could materially impact our financial position or our results of operations in any one quarter.

Revenue Recognition

We recognize revenue from the sale of our products, royalties earned and contract arrangements. Our revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

- We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. Allowances are established for estimated uncollectible amounts, product returns and discounts.
- We recognize revenue from royalties based on licensees' sales of our products or technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees

can be reliably measured and collectibility is reasonably assured. Royalty estimates are made in advance of amounts collected using historical and forecasted trends.

- Contract revenue generally includes upfront and continuing licensing fees, manufacturing fees, milestone payments and reimbursements of development costs and post-marketing costs.
  - Nonrefundable upfront fees, including product opt-ins, for which no further performance obligations exist are recognized as revenue on the earlier of when payments are received or collection is assured.
  - Nonrefundable upfront licensing fees, including product opt-ins, and certain guaranteed, time-based payments that require continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue:
    - ratably over the development period if development risk is significant, or
    - ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated.
  - Manufacturing fees are recognized as revenue as the related manufacturing services are rendered, generally on a straight-line basis over the longer of the manufacturing obligation period or the expected product life.
  - Milestone payments are recognized as revenue when milestones, as defined in the contract, are achieved.
  - Reimbursements of development and post-marketing costs are recognized as revenue as the related costs are incurred.

Income Taxes

Income tax expense (benefit) is based on pretax financial accounting income under the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision (benefit) for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. We believe that our estimates are reasonable and that our reserves for income tax related uncertainties are adequate. Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, future levels of R&D spending, future levels of capital expenditures, and changes in overall levels of pretax earnings.

Inventories

Inventories consist of currently marketed products, products manufactured under contract and product candidates awaiting regulatory approval, which are capitalized based on management's judgment of probable near term commercialization. The valuation of inventory requires us to estimate obsolete or excess inventory. The determination of obsolete or excess inventory requires us to estimate the future demands for our products, and in the case of pre-approval inventories, an estimate of the regulatory approval date for the product. We may be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by the necessary regulatory bodies.

Nonmarketable Equity Securities

As part of our strategic efforts to gain access to potential new products and technologies, we invest in equity securities of certain private biotechnology companies. Our nonmarketable equity securities are carried at cost

unless we determine that an impairment that is other than temporary has occurred, in which case we write the investment down to its impaired value. We periodically review our investments for impairment; however, the impairment analysis requires significant judgment in identifying events or circumstances that would likely have significant adverse effect on the fair value of the investment. The analysis may include assessment of the investee's (i) revenue and earnings trend, (ii) business outlook for its products and technologies, (iii) liquidity position and the rate at which it is using its cash, and (iv) likelihood of obtaining subsequent rounds of financing. If an investee obtains additional funding at a valuation lower than our carrying value, we presume that the investment is other than temporarily impaired. We have experienced impairments in our portfolio due to the decline in equity markets over the past few years. However, we are not able to determine at the present time which specific investments are likely to be impaired in the future, or the extent or timing of the individual impairments.

Results of Operations

(in millions, except per share amounts)

				Annual Percent Change	
	2003	2002	2001	2003/2002	2002/2001
Product sales	$2,621.4	$2,163.6	$1,742.9	21%	24%
Royalties	500.9	365.6	264.5	37	38
Contract revenue	177.9	54.5	36.7	226	49
Total operating revenues	$3,300.2	$2,583.7	$2,044.1	28%	26%
Cost of sales	$ 480.1	$ 441.6	$ 354.5	9%	25%
Research and development	722.0	623.5	526.2	16	18
Marketing, general and administrative	794.8	546.2	446.9	46	22
Collaboration profit sharing	457.5	350.7	246.7	30	42
Recurring charges related to redemption	154.3	155.7	321.8	(1)	(52)
Special items: litigation-related	(113.1)	543.9	—	*	*
Total costs and expenses	$2,495.6	$2,661.6	$1,896.1	(6)%	40%
Operating margin	$ 804.6	$ (77.9)	$ 148.0	*	*
Other income, net	92.8	107.7	135.0	(14)	(20)
Income before taxes and cumulative effect of accounting changes	897.4	29.8	283.0		
Income tax provision (benefit)	287.3	(34.0)	127.1		
Income before cumulative effect of accounting changes	610.1	63.8	155.9		
Cumulative effect of accounting changes, net of tax	(47.6)	—	(5.6)		
Net income	$ 562.5	$ 63.8	$ 150.3		
Pretax operating margin as a % of operating revenues	24%	(3)%	7%		
COS as a % of product sales	18	20	20		
R&D as a % of operating revenues	22	24	26		
MG&A as a % of operating revenues	24	21	22		
NI as a % of operating revenues	17	2	7		

Certain reclassifications were made in 2002 and 2001 to conform to the 2003 presentation. Percentages in this table and throughout our discussion and analysis of financial condition and results of operations may reflect rounding adjustments.

* Calculation not meaningful.

Total Operating Revenues

Total operating revenues increased 28% to $3,300.2 million in 2003 and 26% to $2,583.7 million in 2002. Increases in both years were driven by all components of operating revenues, in particular, higher product sales. These revenue increases are further discussed below *(in millions)*.

				Annual Percent Change	
Product Sales	**2003**	**2002**	**2001**	**2003/2002**	**2002/2001**
Rituxan	$1,489.1	$1,162.9	$ 818.6	28%	42%
Herceptin	424.8	385.2	346.7	10	11
Growth Hormone	321.9	297.2	250.2	8	19
Thrombolytic	185.2	180.2	197.1	3	(9)
Pulmozyme	167.2	138.1	123.0	21	12
Actimmune	—	—	7.3	—	—
Xolair	25.3	—	—	—	—
Raptiva	1.4	—	—	—	—
Product manufactured under contract	6.5	—	—	—	—
Total product sales	$2,621.4	$2,163.6	$1,742.9	21%	24%
Product sales as a % of total operating revenues	79%	84%	85%		

Total Product Sales

Total net product sales increased 21% to $2,621.4 million in 2003 and 24% to $2,163.6 million in 2002. In both years, the increases were due to higher sales across most products, in particular Rituxan. Combined sales of our bio-oncology products, Rituxan and Herceptin, represented 73% of total product sales in 2003, 72% in 2002, and 67% in 2001. Increased sales volume for our products accounted for a 16% increase, or $337.9 million in 2003, and higher sales prices accounted for the remainder of the increase. Increased sales volume for our products accounted for a 20% increase, or $343.3 million in 2002, and higher sales prices accounted for the remainder of the increase. See “Relationship With Roche” and “Related Party Transactions” below for further information about our licensing agreement with and revenue from Hoffmann-La Roche.

Rituxan

Net sales of Rituxan increased 28% to $1,489.1 million in 2003 and 42% to $1,162.9 million in 2002. These increases were primarily driven by higher worldwide sales volume due to increased use of the product for the treatment of B-cell non-Hodgkin’s lymphoma in indolent and aggressive non-Hodgkin’s lymphoma (or NHL), as well as chronic lymphocytic leukemia (or CLL), used in both monotherapy and combination therapy settings. Rituxan’s average overall adoption rate in the combined NHL and CLL markets showed modest growth in 2003. In addition to the above factors, we implemented price increases in both 2003 and 2002, which contributed, to a lesser extent, to the increases.

The current approved label indication is for relapsed or refractory, low grade or follicular NHL. At the 2003 American Society of Hematologists (ASH) meeting, positive data on use of Rituxan in the indolent front line setting were presented. A U.S. Cooperative Group study of Rituxan in the indolent front line NHL setting (ECOG 1496) and an international study of Rituxan in aggressive front line NHL (the MabThera International Trial sponsored by Roche) both reached their efficacy endpoints earlier than planned and were therefore stopped. We expect these factors to continue to positively impact Rituxan sales in 2004, however, the rate of sales growth is expected to be more modest than that seen in 2003 and 2002. Furthermore, future sales of Rituxan may be adversely affected if physicians prescribe less of Rituxan in light of the decrease in the Rituxan reimbursement rate under the Medicare Prescription Drug Improvement and Modernization Act, enacted December 2003 (or the Medicare Act). However, given Rituxan’s unique clinical benefits and lack of a direct substitute therapy, we currently believe there will be limited impact on its usage.

Herceptin

Net sales of Herceptin increased 10% to $424.8 million in 2003 and 11% to $385.2 million in 2002. The 2003 increase was driven by multiple factors, including treating more patients, extending the average treatment duration and a price increase. These increases were slightly offset by a decrease in ex-U.S. Herceptin sales from 2002. First-line penetration has remained stable. However, there has been an increase in the use of Herceptin in more than one line of therapy and we expect this to lead to continued growth in 2004. The increase in 2002 was primarily due to an increase in first-line use in the metastatic breast cancer market and the extension of the average treatment duration. While there was a price increase on sales of Herceptin in the U.S. in 2002, this increase was partially offset by a decrease in the price at which we sell the product to Hoffmann-La Roche. Furthermore, future sales of Herceptin may be adversely affected if physicians prescribe less Herceptin in light of the decrease in the Herceptin reimbursement rate under the Medicare Act. However, we currently believe there will be limited impact on Herceptin's usage, particularly in light of the increase in drug administration services reimbursement rates.

In late September 2002, Hoffmann-La Roche received approval from the European Committee for Proprietary Medicinal Products to manufacture Herceptin at its Penzberg, Germany facility. During 2003, the Penzberg facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories.

Growth Hormone

Combined net sales of our four growth hormone products, Nutropin Depot, Nutropin AQ, Nutropin, and Protropin, increased 8% to $321.9 million in 2003 and 19% to $297.2 million in 2002. The net sales growth resulted from continued strong demand for the products and price increases. The price increase in 2003 accounted for a more significant portion of the growth in 2003 than our 2002 price increase did in 2002. The continued strong demand reflects our focus on new patient starts using our Nutropin AQ Pen (which is a delivery system, launched in July 2002, for Nutropin AQ), continued growth in the adult patient market, higher dosing during puberty and an incremental increase in the length of therapy. Nutropin Depot is a long-acting dosage form of recombinant growth hormone approved for pediatric growth hormone deficiency. Manufacture of Protropin was discontinued at the end of 2002 because physicians are typically initiating therapy with one of the Nutropin family products and the demand for Protropin has declined, but sales are expected to continue through the first half of 2004 or until inventory is depleted.

Thrombolytic

Combined net sales of our three thrombolytic products, Activase, TNKase and Cathflo Activase, increased 3% to $185.2 million in 2003 following a decrease of 9% to $180.2 million in 2002. The increase in 2003 was positively impacted by the implementation of a new business model which took advantage of our comprehensive thrombolytic portfolio and allowed us to focus our marketing efforts on accounts with the highest potential. The higher sales in 2003 were primarily due to Cathflo Activase for catheter clearance. Although Cathflo Activase received FDA approval and was launched in September 2001, we observed an increased acceptance and use of the product in 2003. Additionally, modest increases in Activase usage for acute ischemic stroke were observed. Also contributing to the increase in 2003 were price increases on certain of our thrombolytic products.

The decrease in Activase and TNKase sales in 2002 was attributable to the decline in the overall size of the thrombolytic market, reflecting growth in the peripheral markets (including catheter clearance), the increased use of mechanical reperfusion, and early intervention with other preventive therapies in the treatment of heart attacks. The decrease in 2002 was only partially offset by new sales of Cathflo Activase.

Our sales in 2003 and 2002 were also impacted by continued competition from Centocor, Inc.'s Retavase® (reteplase) and its aggressive price discounting. Competition and declines in the acute myocardial infarction market are expected to be offset by growth in the area of catheter clearance resulting in expected sales of our thrombolytic products in 2004 to be comparable to 2003.

Pulmozyme

Net sales of Pulmozyme increased 21% to $167.2 million in 2003 and 12% to $138.1 million in 2002. These increases primarily reflect an increased focus on aggressive treatment of cystic fibrosis early in the course of the disease and price increases.

Xolair

We received FDA approval to market Xolair in June 2003 and began shipping Xolair in July 2003. Xolair achieved total net sales of $25.3 million in 2003, reflecting distribution of product into the supply channel and positive physician adoption rates. Some physicians feel that the insurance reimbursements they receive for administration of Xolair do not adequately cover their costs and they are working to resolve the issue with insurance providers. Future sales revenue and related expenses are subject to risks and uncertainties, including continued physician adoption rates, third-party payer reimbursement and coverage decisions, and future trial results.

Raptiva

We received FDA approval to market Raptiva in October 2003 and began shipping Raptiva in November 2003. Raptiva achieved total net sales of $1.4 million in 2003, reflecting initial distribution of product into the supply channel and initial reorders. The Raptiva reimbursement model has been received positively. We work with a network of specialty pharmacies in processing reimbursements and the early indications are favorable. Future sales revenue and the continued acceptance of this biologics class are subject to risks and uncertainties, including how well Raptiva is able to compete with other new and established therapies for moderate-to-severe psoriasis.

Royalties

Royalty income increased 37% to $500.9 million in 2003 and 38% to $365.6 million in 2002. The increases in both 2003 and 2002 were due to higher third-party sales by various licensees, primarily Hoffmann-La Roche (see "Related Party Transactions" below) for higher sales of Herceptin and Rituxan products, and gains related to foreign currency exchange rates. The increase in 2002 was also due to new royalties earned under a patent issued to Genentech and our collaborator relating to methods using recombinant DNA technology to make antibodies. We expect that in 2004, the increase in royalty income will be at a slower rate than 2003.

Cash flows from royalty income include revenues denominated in foreign currencies. We currently purchase simple foreign currency put option contracts (or options) to hedge these foreign royalty cash flows. The term of these options is generally one to five years. See the "We Are Exposed to Risks Relating to Foreign Currency Exchange Rates and Foreign Economic Conditions" section of the Forward-Looking Information below for a discussion of market risks related to these financial instruments.

Contract Revenue

Contract revenue increased 226% to $177.9 million in 2003 and 49% to $54.5 million in 2002. The increase in 2003 was primarily driven by revenues from our collaborators for amounts earned on development efforts related to Raptiva, Avastin, Lucentis, Tarceva and Omnitarg, and on upfront payments on new product arrangements for Avastin, Lucentis and PRO70769, a humanized antibody that binds to CD20. The increase in 2002 was primarily due to higher revenues from collaborators, including Hoffmann-La Roche and a new out-licensing arrangement. See "Related Party Transactions" below for more information on contract revenue from Hoffmann-La Roche and Novartis.

We expect that contract revenues will increase in 2004, but at a more modest pace than in 2003. We also expect contract revenues to fluctuate depending on the level of revenues earned for ongoing development efforts, the level of milestones received, the number of new contract arrangements and Hoffmann-La Roche's potential opt-ins for products.

Cost of Sales

Cost of sales (or COS) increased 9% to $480.1 million in 2003 and 25% to $441.6 million in 2002. COS as a percentage of product sales in 2003 was 18%, a decrease from 20% in 2002 and 2001. This decrease primarily reflects higher sales of more favorable margin products (primarily Rituxan and Herceptin) and lower production costs for products sold in 2003.

As mentioned earlier, the Penzberg facility is the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Accordingly, as our ex-U.S. Herceptin sales have declined this year, our cost as a percentage of sales has also declined slightly due to a reduction in the lower gross margins generated by the ex-U.S. Herceptin sales.

As discussed in Part I, Item 1, "Collaboration Arrangements," in December 2003, we entered into an arrangement with Lonza Biologics, a subsidiary of Lonza Group Ltd, to provide additional manufacturing capacity for Rituxan. We do not expect this arrangement to have a significant impact on our overall cost of sales as a percentage of product sales.

COS for products sold to Hoffmann-La Roche totaled $90.6 million in 2003, $99.2 million in 2002 and $63.8 million in 2001.

Research and Development

Research and development (or R&D) expenses increased 16% to $722.0 million in 2003 and 18% to $623.5 million in 2002. R&D as a percentage of operating revenues in 2003 was 22%, a decrease from 24% in 2002 and 26% in 2001. R&D expenses are expected to increase in 2004 as development of and support for our pipeline products increases and as we make full use of our 2003 expansion of our research center in South San Francisco. Coupled with our expectations for higher revenues, R&D as a percentage of operating revenues in 2004 is expected to increase slightly over 2003, but will likely decline over the longer term. We manage our R&D expenses within each of the categories as indicated in the following table and described in more detail below *(in millions)*.

				Annual Percent Change	
Research and Development	**2003**	**2002**	**2001**	**2003/2002**	**2002/2001**
Product development	$449.0	$417.1	$315.7	8%	32%
Post-marketing	81.0	45.5	47.2	78	(4)
Total development	$530.0	$462.6	$362.9	15	27
Research	149.0	131.9	122.5	13	8
In-licensing	43.0	29.0	40.8	48	(29)
Total	$722.0	$623.5	$526.2	16%	18%

Development: Product development expenses include costs of preclinical development and conducting clinical trials. Such costs include costs of personnel, drug supply costs, research fees charged by outside contractors, co-development costs, and facility expenses, including depreciation. Post-marketing expenses include Phase IV and investigator-sponsored trials and product registries. Total development expenses increased 15% to $530.0 million in 2003 and 27% to $462.6 million in 2002.

The increase in 2003 was largely due to higher spending of $31.9 million by us and our collaborators on the clinical development of our pipeline products, including Lucentis, Herceptin, Omnitarg and Rituxan Immunology, partially offset by less spending on Xolair, which was launched in July 2003. We also had in 2003 an increase of $35.5 million related to Phase IV and investigator-sponsored trials for products, including Raptiva, Avastin and Xolair.

The increase in 2002 was primarily due to higher clinical development expenses related to projects primarily in late-stage development, including $14.1 million for Tarceva, $10.0 million for Avastin, $8.4 million for Raptiva, $6.7 million for Xolair and $2.9 million for Lucentis. The increase in 2002 was also due to increased manufacturing of pre-approval development products, including Avastin, and process implementation for contract manufacturing for Immunex Corporation, a wholly-owned subsidiary of Amgen. See discussion on ENBREL in Part I, Item 1, "Collaboration Arrangements."

Biopharmaceutical products that we develop internally generally take 10 to 15 years (an average of 12 years) to research, develop and bring to market a new prescription medicine in the United States. Drug development in the U.S. is a process that includes several steps defined by the FDA. The process begins with the filing of an Investigation New Drug Application (or IND) which, if successful, allows opportunity for clinical study of the potential new medicine. Clinical development typically involves three phases of study: Phase I, II, and III, and we have found that it accounts for an average of seven years of a drug's total development time. The most significant costs associated with clinical development are the Phase III trials as they tend to be the longest and largest studies conducted during the drug development process. The successful development of our products is highly uncertain. An estimation of product completion dates and completion costs can vary significantly for each product and are difficult to predict. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could have a material adverse affect on our business. In responding to a New Drug Application (or NDA) or a Biologic License Application (or BLA), the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. We cannot assure you that any approval required by the FDA will be obtained on a timely basis, if at all. For additional discussion of the risks and uncertainties associated with completing development of potential products, see "The Successful Development of Biotherapeutics is Highly Uncertain and Requires Significant Expenditures" section of our Forward-Looking Information below. See Part I, Item 1 of this Form 10-K for a summary of our products in development and their related stages.

We have established strategic alliances with various companies to gain additional access to potential new products and technologies, and to utilize companies to help develop potential new products. These companies are developing technologies that may fall outside of our research focus; through technology exchanges and investments with these companies, we may have the potential to generate new products. As part of certain of these strategic alliances, we have acquired equity or convertible debt securities of such companies. We have also entered into product-specific collaborations to acquire development and marketing rights for potential products. See discussion in Part I, Item 1, "Collaboration Arrangements."

Research: Research includes expenses associated with research and testing of our product candidates prior to reaching the development stage. Such expenses primarily include the costs of internal personnel, outside contractors, facilities, including depreciation, and lab supplies. Personnel costs primarily include salary, fringe benefits, recruiting and relocation costs. Research expenses increased 13% to $149.0 million in 2003 and 8% to $131.9 million in 2002. The primary driver of the increase in both years was an increase in internal personnel and outside contractors for research and testing of product candidates.

In-licensing: In-licensing includes costs to acquire licenses to develop and commercialize various technologies and molecules. In-licensing expenses increased 48% to $43.0 million in 2003 and decreased 29% to $29.0 million in 2002. The increase in 2003 was primarily due to new collaborations, including $13.6 million of upfront payments for the purchase of in-process research and development (or IPR&D) under in-licensing agreements. This 2003 IPR&D expense, $4.0 million in 2002 and $19.0 million in 2001 represent acquired IPR&D that was not yet technologically feasible and had no future uses, and therefore was expensed. Of the $19.0 million of IPR&D in 2001, $15.0 million relates to an upfront payment to OSI Pharmaceuticals, Inc. (or OSI) under an agreement with us, OSI and Hoffmann-La Roche for the global co-development and

commercialization of Tarceva for the potential treatment of solid tumor cancers. One of the members of the Board of Directors of OSI is also a member of the Board of Directors of Genentech.

Marketing, General and Administrative

Marketing, general and administrative (or MG&A) expenses increased 46% to $794.8 million in 2003 and 22% to $546.2 million in 2002. The increase in 2003 was due to: (i) a $127.6 million increase in marketing activities and headcount expenses primarily related to the launch of Xolair and Raptiva and launch preparations for Avastin; (ii) a $59.3 million increase related to headcount growth and increased commercial training programs in support of all products, including increases in field sales bonus expenses; (iii) a $43.6 million increase in corporate bonus and corporate functional expenses (primarily related to information systems technologies), and increased headcount and related expenses across most corporate functions, partially offset by lower fixed asset disposals, and (iv) an $18.2 million increase in royalty expenses, primarily related to Biogen Idec.

The increase in 2002 was primarily related to higher general and administrative (or G&A) expense. The increase in G&A was primarily due to a $32.5 million increase in royalty expenses associated with higher sales by various licensees for which we have royalty obligations and a $15.9 million charge primarily for the redesign of research facilities, and the write-off of building improvements and equipment. These increases were partially offset by a $9.3 million reimbursement of legal costs. Marketing and sales expense was higher by $40.0 million in 2002 as compared to 2001 primarily in support of our bio-oncology and pipeline products, new information technology and increased headcount in support of all products.

MG&A expenses are expected to rise in the near term, in particular, the marketing and sales component as we continue to market our newer products, Xolair and Raptiva and as we launch Avastin in early 2004. However, as we expect revenues to rise, MG&A as a percentage of operating revenues will likely decline over the longer term.

Collaboration Profit Sharing

Collaboration profit sharing consists primarily of the net operating profit sharing with Biogen Idec on commercial activities underlying Rituxan sales and, to a much lesser extent, the sharing of the commercial net operating results of Xolair with Novartis. Collaboration profit sharing expenses increased 30% to $457.5 million in 2003 and 42% to $350.7 million in 2002. These increases were primarily driven by increased Rituxan profit sharing with Biogen Idec due to higher Rituxan sales.

Collaboration profit sharing expense is expected to increase in 2004 consistent with the expected collaboration operating results associated with increased Rituxan and Xolair sales.

Recurring Charges Related to Redemption

We began recording recurring charges related to the Redemption and push-down accounting in the third quarter of 1999. In 2003 and 2002, these charges were comprised of the amortization of other intangible assets. In 2001, these charges were primarily comprised of to the amortization of other intangible assets and goodwill. See also the “Redemption of our Special Common Stock” note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

On January 1, 2002, we adopted Statement of Financial Accounting Standards (or FAS) 141, “Business Combinations” and FAS 142, “Goodwill and Other Intangible Assets.” In accordance with FAS 141 and 142, we discontinued the amortization of goodwill and our trained and assembled workforce intangible asset, which resulted in an increase in reported net income by approximately $157.6 million (or $0.30 per share) in 2002 as compared to the accounting prior to the adoption of FAS 141 and 142. We performed an impairment test of goodwill at transition on January 1, 2002, and an annual impairment test on September 30, 2003 and 2002, and

found no impairment. We will continue to evaluate our goodwill for impairment on an annual basis each September and whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. See also the "Goodwill and Other Intangible Assets" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

Special Items: Litigation-Related

In August 2003, we settled our patent litigation with Amgen, Inc. in the U.S. District Court for the Northern District of California. The settlement of our complaint, originally filed in 1996, resulted in a one-time payment from Amgen to us. The settlement resulted in an increase of approximately $0.19 in earnings per diluted share for 2003 and was reported as a litigation-related special item in our consolidated statements of income. In November 2003, we received a settlement payment from Bayer, one of our licensees, in connection with the settlement of a breach of contract action which resulted in an increase of approximately $0.03 in earnings per diluted share for 2003 and was reported as a litigation-related special item. In addition, we recognized $53.9 million in 2003 for accrued interest and bond costs related to the City of Hope National Medical Center (or COH) trial judgment described further below.

In 2002, we recognized $543.9 million of litigation-related special charges. These special charges were comprised of the COH litigation judgment including accrued interest and costs related to obtaining a surety bond and certain other litigation-related matters. We expect that we will continue to incur interest charges on the judgment and service fees on the surety bond each quarter through the process of appealing the COH trial results. These special charges represent our estimate of the costs for the current resolution of these matters and are included in litigation and other long-term liabilities in the consolidated balance sheet at December 31, 2003 and 2002. We developed this estimate in consultation with outside counsel handling our defense in these matters and the estimate is based upon the facts and circumstances of these matters known to us at that time. The amount of our liability for certain of these matters could exceed or be less than the amount of our current estimate, depending on the outcome of these matters. The amount of cash, if any, to be paid in connection with the COH matter will depend on the outcome of the appeal. See the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding our litigations.

Other Income, Net

As part of our strategic alliance efforts, we invest in debt and equity securities of certain biotechnology companies with which we have or have had collaborative agreements. "Other income, net" includes realized gains and losses from the sale of certain of these biotechnology equity securities as well as changes in the recoverability of our debt securities. In addition, "other income, net" includes write-downs for other-than-temporary declines in the fair value of certain of these biotechnology debt and equity securities, interest income and interest expense, net of amounts capitalized in 2002 and 2001.

				Annual Percent Change	
Other Income, Net	**2003**	**2002**	**2001**	**2003/2002**	**2002/2001**
		(in millions)			
Gains on sales of biotechnology equity securities and other	$21.1	$ 47.9	$ 37.7	(56)%	27%
Write-downs of biotechnology debt and equity securities	(3.8)	(40.8)	(27.5)	(91)	48
Interest income	78.4	101.4	130.5	(23)	(22)
Interest expense	(2.9)	(0.8)	(5.7)	263	(86)
Total other income, net	$92.8	$107.7	$135.0	(14)%	(20)%

"Other income, net" decreased 14% to $92.8 million in 2003 and 20% to $107.7 million in 2002. The decrease in 2003 was due to lower gains on sales of biotechnology equity securities coupled with a favorable change in the

recoverability of a previously written-down debt security in 2002. Also contributing to the year-to-year decrease was lower interest income as a result of lower investment portfolio yields, which was partially offset by higher average portfolio balances. The decrease over 2002 was partially offset by the favorable effect of lower write-downs of our biotechnology equity securities due to overall improved market conditions in 2003. Although we have had minimal biotechnology marketable equity security write-downs in 2003, we may determine in future periods, depending on market conditions, that certain of such unhedged securities are impaired and require a write-down to market value.

The decrease in 2002 was due to lower interest income due to lower portfolio yields and, to a lesser extent, lower average portfolio balances. The lower portfolio balances were primarily due to the repurchase of 18.2 million shares of our common stock at a cost of approximately $692.8 million during 2002. (See the "Capital Stock" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.) The year over year decrease was also due to an increase in write-downs of biotechnology debt and equity securities due to the decline in the overall market conditions in 2002. These unfavorable variances were partially offset by a favorable change in the recoverability of a previously written-down debt security and higher gains from the sale of biotechnology equity securities, and lower interest expense in 2002. The decrease in interest expense was a result of the repayment of our debentures, which matured in March 2002, and were redeemed in cash. See the "Debt Obligations" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding these debentures.

Income Tax Provision (Benefit)

The income tax provision of $287.3 million in 2003 differed from the income tax benefit of $34.0 million in 2002 primarily due to increased 2003 pretax income. The income tax benefit in 2002 differed from the income tax provision of $127.1 million in 2001 primarily due to substantially reduced pretax income and the elimination of non-deductible goodwill pursuant to the adoption of FAS 141 and FAS 142 in January 2002. The 2001 income tax provision reflects decreased benefit of R&D tax credits, which was offset by prior years' items. Prior years' items relate principally to changes in estimates resulting from events that provided greater certainty as to the expected outcome of these matters.

Our 2004 tax rate is expected to be approximately 35% for the year, an increase from 32% in 2003. This is due to favorable changes in estimates from prior years' items and foreign revenue items affecting the tax rate in 2003 but not in 2004. Other factors may have favorable or unfavorable effects upon our effective tax rate in 2004 and subsequent years. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, future levels of R&D spending, future levels of capital expenditures and changes in overall levels of pretax earnings.

Cumulative Effect of Accounting Changes and Other Changes in Accounting Principles

Financial Accounting Standards Board (or FASB) Interpretation No. 46 (or FIN 46) "Consolidation of Variable Interest Entities," as amended, an interpretation of Accounting Research Bulletin No. 51, issued in January 2003, requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIE's expected losses, receives a majority of the entity's expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003, however, the FASB deferred the effective date for VIEs created before February 1, 2003 to the quarter ended March 31, 2004 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted.

We adopted FIN 46 on July 1, 2003, and consolidated the entity from which we lease our manufacturing facility located in Vacaville, California as of that date, as we determined that this entity is a VIE, as defined by FIN 46, and that we absorb a majority of its expected losses. Accordingly, we consolidated assets, which consist of the Vacaville manufacturing building and related equipment, net of accumulated depreciation. Such property and

equipment had a carrying value of $348.4 million at December 31, 2003 and was included in property, plant and equipment in the accompanying consolidated balance sheet. We also consolidated the entity's debt of $412.3 million and noncontrolling interests of $12.7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, in the accompanying consolidated balance sheet at December 31, 2003. We recorded a $47.6 million charge, net of $31.8 million in taxes, (or $0.09 per share) as a cumulative effect of the accounting change in the third quarter of 2003. We had previously accounted for our involvement with this entity as an operating lease. See also "Leases" below for a discussion of all of our leases.

On January 1, 2002, we adopted FAS 141, "Business Combinations" and FAS 142, "Goodwill and Other Intangible Assets." Under the new rules, goodwill is no longer amortized but is subject to an impairment test at least annually. FAS 141 specifically identified assembled workforce as an intangible asset that is not to be recognized apart from goodwill and it was subsumed into goodwill on January 1, 2002. In accordance with FAS 141 and 142, we discontinued the amortization of goodwill and our trained and assembled workforce intangible asset, which resulted in an increase in reported net income by approximately $157.6 million (or $0.30 per share) in 2002, as compared to the accounting prior to the adoption of FAS 141 and 142. See also the "Goodwill and Other Intangible Assets" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

See also the "Description of Business and Summary of Significant Accounting Policies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for information on our adoption of FAS 141, 142, and FIN 46.

We adopted FAS 133, "Accounting for Derivative Instruments and Hedging Activities," on January 1, 2001. Upon adoption, we recorded a $5.6 million charge, net of $3.8 million in taxes, ($0.01 per share) as a cumulative effect of a change in accounting principle, recognized $6.0 million in gains, net of $4.0 million in taxes, ($0.01 per share) in "other income, net" related to certain hedging instruments and increased other comprehensive income by $5.0 million, net of $3.3 million in taxes, as a result of recording derivative instruments at fair value.

The effects of the accounting changes described above are as follows *(in millions, except per share amounts)*:

Net Income and Earnings Per Share	**2003**	**2002**	**2001**
Net income	$562.5	$63.8	$150.3
Earnings per share:			
Basic:			
Earnings before cumulative effect of accounting changes	1.18	0.12	0.30
Cumulative effect of accounting changes, net of tax	(0.09)	—	(0.01)
Net earnings per share	$ 1.09	$0.12	$ 0.29
Diluted:			
Earnings before cumulative effect of accounting changes	$ 1.15	$0.12	$ 0.29
Cumulative effect of accounting changes, net of tax	(0.09)	—	(0.01)
Net earnings per share	$ 1.06	$0.12	$ 0.28

Net Income and Earnings Per Share

Net income increased in 2003 to $562.5 million, or $1.06 per diluted share, from a net income in 2002 of $63.8 million, or $0.12 per diluted share. The increase was primarily due to changes in year-to-date litigation-related special items from charges of $543.9 million in 2002 to settlement receipts (net of charges) of $113.1 million in 2003. Also contributing to the increase were higher operating revenues in 2003, driven mostly by higher product sales, partially offset by higher operating expenses in 2003.

Net income decreased in 2002 to $63.8 million, or $0.12 per diluted share, from a net income of $150.3 million in 2001, or $0.28 per diluted share. The decrease primarily reflects the 2002 litigation-related special charges,

and also reflects increased collaboration profit sharing, R&D, MG&A and COS expenses and decreased "other income, net." These unfavorable changes were partially offset by increased product sales, royalties and contract revenues and decreased recurring charges related to the Redemption.

In-Process Research and Development

At June 30, 1999, the Redemption date, we determined that the acquired in-process technology was not technologically feasible and that the in-process technology had no future alternative uses. In 1990 and 1991 through 1997, Roche Holdings, Inc. (or Roche) purchased 60% and 5%, respectively, of our outstanding common stock. The push-down effect of Roche's aggregate purchase price is allocated based on Roche's ownership percentages as if the purchases had occurred at the original purchase dates for the 1990 and 1991 through 1997 purchases. Therefore, 65% of the purchase price allocated to IPR&D as of September 7, 1990, or 65% of $770.0 million ($500.5 million) was recorded as an adjustment to additional paid-in capital related to the 1990-1997 acquisitions. The remaining 35% of our outstanding common stock not owned by Roche was purchased in 1999. Accordingly, 35% of $2,150.0 million of total fair value at the Redemption date, or $752.5 million, was expensed on June 30, 1999.

The amounts of IPR&D were determined based on an analysis using the risk-adjusted cash flows expected to be generated by the products that result from the in-process projects. The analysis included forecasted future cash flows that were expected to result from the progress made on each of the in-process projects prior to the purchase dates. These cash flows were estimated by first forecasting, on a product-by-product basis, total operating revenues expected from sales of the first generation of each in-process product. A portion of the gross in-process product revenues was then removed to account for the contribution provided by any core technology, which was considered to benefit the in-process products. The net in-process revenue was then multiplied by the project's estimated percentage of completion as of the purchase dates to determine a forecast of net IPR&D revenues attributable to projects completed prior to the purchase dates. Appropriate operating expenses, cash flow adjustments and contributory asset returns were deducted from the forecast to establish a forecast of net returns on the completed portion of the in-process technology. Finally, these net returns were discounted to a present value at discount rates that incorporate both the weighted-average cost of capital (relative to the biotech industry and us) as well as the product-specific risk associated with the purchased IPR&D products. The product-specific risk factors included each product in each phase of development, type of molecule under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, pre-clinical safety and efficacy data, target product profile and development plan. The discount rates ranged from 16% to 19% for the 1999 valuation and 20% to 28% for the 1990 purchase valuation, all of which represent a significant risk premium to our weighted-average cost of capital.

The forecast data in the analysis was based on internal product level forecast information maintained by our management in the ordinary course of managing the business. The inputs used by us in analyzing IPR&D were based on assumptions, which we believed to be reasonable but which were inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur.

A brief description of projects that were included in the IPR&D charge is set forth below, including an estimated percentage of completion as of the Redemption date. Projects subsequently added to the research and development pipeline are not included. Except as otherwise noted below, since the Redemption date there have been no significant changes to the phase of development for the projects listed. We do not track all costs associated with research and development on a project-by-project basis. Therefore, we believe a calculation of cost incurred as a percentage of total incurred project cost as of FDA approval is not possible. We estimate, however, that the R&D expenditures required to complete the in-process projects will total at least $240.0 million as of December 31, 2003, as compared to $700.0 million as of the Redemption date. This estimate reflects costs incurred since the Redemption date, discontinued projects, and decreases in cost to complete estimates for other projects, partially offset by an increase in certain cost estimates related to early stage projects and changes in expected completion dates.

At the Redemption date, we estimated percentage complete data for each project based on the weighing of three indicators, as follows:

PTS: Probability of technical success (or PTS) is a project level statistic maintained by us on an ongoing basis, which is intended to represent the current likelihood of project success, i.e., FDA approval. This is a quantitative calculation based on the stage of development and the complexity of the project, and it is highly correlated with the project's phase of development. PTS is periodically adjusted to reflect actual experiences over a reasonable period of time.

Status Compared to Baseline Model: We developed a baseline model, which allocated percentages of a standard development project to each major phase of the project based on our experience. We then overlaid the time-based status of each project to this baseline model, in order to calculate a percentage complete for each project.

Management's Estimate of Percentage Complete: Below is a list of the projects and their estimated percentage complete included in the IPR&D charge related to the Redemption:

		As of the Redemption Date, June 30, 1999		
Product	**Description/Indication**	**Phase of Development**	**Substantial Completion Date**	**% Complete**
Nutropin Depot	long-acting dosage form of recombinant growth hormone	Awaiting regulatory approval	2000	85%
TNKase, second generation t-PA	acute myocardial infarction	Awaiting regulatory approval	2000	90%
Xolair (formerly Anti-IgE antibody)	allergic asthma, seasonal allergic rhinitis	Phase III	2001	75%
Pulmozyme	early-stage cystic fibrosis	Phase III	2003	75%
Dornase alfa AERx™ Delivery System	cystic fibrosis	Preparing for Clinical Testing	2003	45%
Rituxan antibody	aggressive non-Hodgkin's lymphoma	Phase III	2004	60%
Xubix (sibrafiban) oral IIb/IIIa antagonist	orally administered inhibitor of platelet aggregation	Phase III	2000	65%
Cathflo Activase t-PA	intravenous catheter clearance	Preparing for Phase III	1999	90%
Raptiva (formerly Anti-CD11a antibody and hull24)	psoriasis	Preparing for Phase III	2003	50%
Herceptin antibody	adjuvant therapy for breast cancer	Preparing for Phase III	2007	45%
Thrombopoietin (TPO)	thrombocytopenia related to cancer treatment	Preparing for Phase III	2002	55%
Anti-CD18 antibody	acute myocardial infarction	Phase II	2004	55%
Avastin (Anti-VEGF antibody)	colorectal and lung cancer	Phase II	2003	35-40%
Herceptin antibody	other tumors	Phase II	2004	40-45%
Lucentis (formerly rhuFab V2 AMD)	age-related macular degeneration	Preparing for Phase I	2004	20%
MLN-02 antibody (formerly LDP-02)	inflammatory bowel disease	Phase Ib/IIa	2005	30%

We also identified five additional product programs that were at different stages of IPR&D. As of June 30, 1999, the Redemption date, we estimated that these projects would be substantially complete in years 1999 through 2004. The percent completion for each of these additional programs ranged from an estimated 35% to 90%. These projects did not receive material allocations of the purchase price.

In addition, our IPR&D at the Redemption date included a process technology program. The process technology program included the R&D of ideas and techniques that could improve the bulk production of antibodies, including cell culture productivity, and streamlined and improved recovery processes, and improvements in various areas of pharmaceutical manufacturing. We estimated that the process technology program was approximately 50% complete at the Redemption date. Material cash inflows from significant projects are generally expected to commence within one to two years after the substantial completion date has been reached.

The significant changes to the projects included in the IPR&D charge since the Redemption date include:

- Nutropin Depot — We announced on December 23, 1999, that Nutropin Depot received approval from the FDA for pediatric growth hormone deficiency (GHD).
- TNKase (tenecteplase) — We announced on June 2, 2000, that TNKase, a single-bolus thrombolytic agent, was approved by the FDA for the treatment of acute myocardial infarction (AMI).
- Xolair (omalizumab) — We announced on June 20, 2003, that the FDA approved Xolair for the treatment of moderate-to-severe persistent asthma in adults and adolescents. We began shipping Xolair in July 2003.
- Pulmozyme — Phase III trial in early stage cystic fibrosis has been completed and the study results were published in December 2001.
- Dornase alfa AERx — This project has been discontinued.
- Rituxan (rituximab) — We and Biogen Idec, Inc. are conducting a Phase III randomized study of Rituxan as a front-line and maintenance therapy in the treatment of newly diagnosed, diffuse, large, B-cell, or aggressive non-Hodgkin's lymphoma (NHL).
- Xubix (sibrafiban) oral IIb/IIIa antagonist — This project has been discontinued.
- Cathflo Activase t-PA — We announced on September 4, 2001, that Cathflo Activase was approved by the FDA for the restoration of function to central venous access devices (CVADs), as assessed by the ability to withdraw blood.
- Raptiva (efalizumab) — We announced on May 12, 2003, in co-development with XOMA Ltd., the decision to terminate Phase II testing of Raptiva in patients with moderate-to-severe rheumatoid arthritis. We and XOMA announced on October 27, 2003, that Raptiva has been approved by the FDA for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy.
- Herceptin (trastuzumab) — Phase III program studying Herceptin as an adjuvant therapy for breast cancer may take longer to complete than originally anticipated.
- Thrombopoietin (or TPO) — There is an agreement with Pharmacia that development efforts will be discontinued.
- Anti-CD18 antibody — This project has been discontinued.
- Avastin (bevacizumab) — We announced on February 26, 2004, that the FDA approved Avastin to be used in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first-line (or previously untreated) metastatic cancer of the colon or rectum. We began shipping Avastin on February 26, 2004.
- Herceptin antibody for non-small cell lung cancer (or NSCLC) — This project has been discontinued for this indication.

- Lucentis (ranibizumab) — We have initiated two Phase III studies for patients with the wet form of age-related macular degeneration. On June 24, 2003, we announced that Novartis Ophthalmics, the eye health unit of Novartis AG, would receive an exclusive license to develop and market Lucentis outside of North America for indications related to diseases of the eye.
- MLN-02 antibody — We announced on October 8, 2003, that after a review of the Phase II ulcerative colitis data results, Genentech and Millennium Pharmaceuticals, Inc. have decided not to move forward with a Phase III study at this time. The companies are currently in discussions regarding next steps with the MLN-02 program.

Item 1 and Item 7 of this 10-K contains forward-looking statements regarding timing of completion of phases for projects in product development, costs related to the completion of in-process projects, time frame of Rituxan manufacturing by Lonza and Avastin manufacturing at Porrino, higher revenues, sales of Rituxan and Herceptin, royalties, contract revenues, R&D expenses, MG&A and collaboration profit sharing expenses, capital expenditures and impact of Medicare legislation on our sales of Rituxan and Herceptin. Actual results could differ materially. For a discussion of the risks and uncertainties associated with the time frame of Rituxan manufacturing by Lonza and Avastin manufacturing at Porrino, see "The Successful Development of Biotherapeutics is Highly Uncertain and Requires Significant Expenditures," "We May Be Unable to Obtain or Maintain Regulatory Approvals for Our Products," "Difficulties or Delays in Product Manufacturing Could Harm Our Business," and "We May Be Unable to Manufacture Certain of Our Products If There Is BSE Contamination of Our Bovine Source Raw Material" sections of "Forward-Looking Information and Cautionary Factors That May Affect Future Results" (or "Forward-Looking Information"); the timing of completion of product development phases, costs related to the completion of in-process projects, R&D expenses and capital expenditures, see all of the foregoing and "Protecting Our Proprietary Rights Is Difficult and Costly," "The Outcome of, and Costs Relating to, Pending Litigation or Other Legal Actions are Uncertain," and "We May Be Unable to Retain Skilled Personnel and Maintain Key Relationships"; for the impact of Medicare legislation, see "Decreases in Third Party Reimbursement Rates May Affect Our Product Sales"; for sales of Rituxan and Herceptin and MG&A and collaboration profit sharing expenses, see all of the foregoing and "We Face Competition," "Other Factors Could Affect Our Product Sales," "We May Incur Material Product Liability Costs," "Insurance Coverage is Increasingly More Difficult to Obtain or Maintain," and "We Are Subject to Environmental and Other Risks"; for royalties and contract revenues, see "Our Royalty and Contract Revenues Could Decline"; and for higher revenues, see all of the foregoing of Forward-Looking Information below. The Company has no intention and disclaims any obligation, to update or revise any forward-looking statements discussed above.

RELATIONSHIP WITH ROCHE

As a result of the Redemption of our Special Common Stock, the then-existing governance agreement between us and Roche terminated, except for provisions relating to indemnification and stock options, warrants and convertible securities. In July 1999, we entered into certain affiliation arrangements with Roche, amended our licensing and marketing agreement with Hoffmann-La Roche, and entered into a tax sharing agreement with Roche as follows:

Affiliation Arrangements

Our board of directors consists of two Roche directors, three independent directors nominated by a nominating committee currently controlled by Roche, and one Genentech employee. However, under our bylaws, Roche has the right to obtain proportional representation on our board at any time. Roche intends to continue to allow our current management to conduct our business and operations as we have done in the past. However, we cannot ensure that Roche will not implement a new business plan in the future.

Except as follows, the affiliation arrangements do not limit Roche's ability to buy or sell our Common Stock. If Roche and its affiliates sell their majority ownership of shares of our Common Stock to a successor, Roche has

agreed that it will cause the successor to agree to purchase all shares of our Common Stock not held by Roche as follows:

- with consideration, if that consideration is composed entirely of either cash or equity traded on a U.S. national securities exchange, in the same form and amounts per share as received by Roche and its affiliates; and
- in all other cases, with consideration that has a value per share not less than the weighted-average value per share received by Roche and its affiliates as determined by a nationally recognized investment bank.

If Roche owns more than 90% of our Common Stock for more than two months, Roche has agreed that it will, as soon as reasonably practicable, effect a merger of Genentech with Roche or an affiliate of Roche.

Roche has agreed, as a condition to any merger of Genentech with Roche or the sale of our assets to Roche, that either:

- the merger or sale must be authorized by the favorable vote of a majority of non-Roche stockholders, provided no person will be entitled to cast more than 5% of the votes at the meeting; or
- in the event such a favorable vote is not obtained, the value of the consideration to be received by non-Roche stockholders would be equal to or greater than the average of the means of the ranges of fair values for the Common Stock as determined by two nationally recognized investment banks.

We have agreed not to approve, without the prior approval of the directors designated by Roche:

- any acquisition, sale or other disposal of all or a portion of our business representing 10% or more of our assets, net income or revenues;
- any issuance of capital stock except under certain circumstances; or
- any repurchase or redemption of our capital stock other than a redemption required by the terms of any security and purchases made at fair market value in connection with any of our deferred compensation plans.

Licensing Agreement

We have a licensing and marketing agreement with Hoffmann-La Roche and its affiliates granting an option to license, use and sell our products in non-U.S. markets. The major provisions of that agreement include the following:

- Hoffmann-La Roche's option expires in 2015;
- Hoffmann-La Roche may exercise its option to license our products upon the occurrence of any of the following: (1) our decision to file an IND for a product, (2) completion of a Phase II trial for a product or (3) if Hoffmann-La Roche previously paid us a fee of $10.0 million to extend its option on a product, completion of a Phase III trial for that product;
- if Hoffmann-La Roche exercises its option to license a product, it has agreed to reimburse Genentech for development costs as follows: (1) if exercise occurs at the time an IND is filed, Hoffmann-La Roche will pay 50% of development costs incurred prior to the filing and 50% of development costs subsequently incurred, (2) if exercise occurs at the completion of a Phase II trial, Hoffmann-La Roche will pay 50% of development costs incurred through completion of the trial, 75% of development costs subsequently incurred for the initial indication, and 50% of subsequent development costs for new indications, formulations or dosing schedules, (3) if the exercise occurs at the completion of a Phase III trial, Hoffmann-La Roche will pay 50% of development costs incurred through completion of Phase II, 75% of development costs incurred through completion of Phase III, and 75% of development costs subsequently incurred, and $5.0 million of the option extension fee paid by Hoffmann-La Roche to

preserve its right to exercise its option at the completion of a Phase III trial will be credited against the total development costs payable to Genentech upon the exercise of the option, and (4) each of Genentech and Hoffmann-La Roche have the right to "opt-out" of developing an additional indication for a product for which Hoffmann-La Roche exercised it option, and would not share the costs or benefits of the additional indication, but could "opt-back-in" before approval of the indication by paying twice what they would have owed for development of the indication if they had not opted out;

- we agreed, in general, to manufacture for and supply to Hoffmann-La Roche its clinical requirements of our products at cost, and its commercial requirements at cost plus a margin of 20%; however, Hoffmann-La Roche will have the right to manufacture our products under certain circumstances, and in late September 2002, Hoffmann-La Roche received approval from the European Committee for Proprietary Medicinal Products to manufacture Herceptin at its Penzberg, Germany facility; during 2003, the Penzberg facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories;
- Hoffmann-La Roche has agreed to pay, for each product for which Hoffmann-La Roche exercises its option upon either a decision to file an IND with the FDA or completion of the Phase II trials, a royalty of 12.5% on the first $100.0 million on its aggregate sales of that product and thereafter a royalty of 15% on its aggregate sales of that product in excess of $100.0 million until the later in each country of the expiration of our last relevant patent or 25 years from the first commercial introduction of that product; and
- Hoffmann-La Roche will pay, for each product for which Hoffmann-La Roche exercises its option after completion of the Phase III trials, a royalty of 15% on its sales of that product until the later in each country of the expiration of our relevant patent or 25 years from the first commercial introduction of that product; however, $5.0 million of any option extension fee paid by Hoffmann-La Roche will be credited against royalties payable to us in the first calendar year of sales by Hoffmann-La Roche in which aggregate sales of that product exceed $100.0 million.

Tax Sharing Agreement

Since the redemption of our Special Common Stock in June 1999, and until Roche completed its second public offering of our Common Stock in October 1999, we were included in Roche's U.S. federal consolidated group and state and local consolidated or combined income tax groups. Accordingly, we entered into a tax sharing agreement with Roche. Pursuant to the tax sharing agreement, we and Roche were to make payments such that the net amount paid by us on account of federal consolidated and state and local consolidated or combined income taxes was determined as if we had filed separate, stand-alone federal, state and local income tax returns as the common parent of an affiliated group of corporations filing consolidated or combined federal, state and local returns.

Effective with the consummation of the second public offering on October 26, 1999, we ceased to be a member of the consolidated federal income tax group (and certain state and local consolidated or combined income tax groups) of which Roche is the common parent. Accordingly, our tax sharing agreement with Roche now pertains only to the state and local tax returns in which we are consolidated or combined with Roche. We will continue to calculate our tax liability or refund with Roche for these state and local jurisdictions as if we were a stand-alone entity.

Roche's Ability to Maintain Its Percentage Ownership Interest in Our Stock

We expect from time to time to issue additional shares of common stock in connection with our stock option and stock purchase plans, and we may issue additional shares for other purposes. Our affiliation agreement with Roche provides, among other things, that we establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. The affiliation agreement provides that we will repurchase a

sufficient number of shares pursuant to this program such that, with respect to any issuance of common stock by Genentech in the future, the percentage of Genentech common stock owned by Roche immediately after such issuance will be no lower than Roche's lowest percentage ownership of Genentech common stock at any time after the offering of common stock occurring in July 1999 and prior to the time of such issuance, except that Genentech may issue shares up to an amount that would cause Roche's lowest percentage ownership to be no more than 2% below the "Minimum Percentage." The Minimum Percentage equals the lowest number of shares of Genentech common stock owned by Roche since the July 1999 offering (to be adjusted in the future for dispositions of shares of Genentech common stock by Roche as well as for stock splits or stock combinations) divided by 509,194,352 (to be adjusted in the future for stock splits or stock combinations), which is the number of shares of Genentech common stock outstanding at the time of the July 1999 offering, as adjusted for the two-for-one splits of Genentech common stock in November 1999 and October 2000. We have repurchased shares of our common stock in 2003 (see discussion below in Liquidity and Capital Resources). As long as Roche's percentage ownership is greater than 50%, prior to issuing any shares, the affiliation agreement provides that we will repurchase a sufficient number of shares of our common stock such that, immediately after our issuance of shares, Roche's percentage ownership will be greater than 50%. The affiliation agreement also provides that, upon Roche's request, we will repurchase shares of our common stock to increase Roche's ownership to the Minimum Percentage. In addition, Roche will have a continuing option to buy stock from us at prevailing market prices to maintain its percentage ownership interest. On December 31, 2003, Roche's percentage ownership of our common stock was 58.4%, which was 1.8% below the Minimum Percentage.

RELATED PARTY TRANSACTIONS

Roche

We enter into transactions with Roche, Hoffmann-La Roche and its affiliates in the ordinary course of business. The accounting policies we apply to our transactions with Roche and its affiliates are consistent with those used in transactions with independent third-parties.

In June 2003, Hoffmann-La Roche exercised its option to license from us the rights to market Avastin for all countries outside of the U.S. under its existing licensing agreement with us. As part of its opt-in, Hoffmann-La Roche paid us approximately $188.0 million and will pay 75% of subsequent global development costs related to the metastatic colorectal cancer indication of Avastin and all others unless Hoffmann-La Roche specifically opts out of the development of certain other indications.

In September 2003, Hoffmann-La Roche exercised its option to license from us the rights to market PRO70769, a humanized antibody that binds to CD20, for all countries outside of the U.S. (other than territory previously committed to others) under the existing licensing agreement. As part of its opt-in, Hoffmann-La Roche paid us $8.4 million and will pay 50% of subsequent global development costs related to PRO70769 unless Roche opts out of the development of certain indications. We will receive royalties on net sales of Avastin and PRO70769 in countries outside of the U.S.

As part of our licensing and marketing agreement, we recognized milestone-related royalty revenue of $20.0 million in 2003 and $10.0 million in 2002 as a result of Hoffmann-La Roche reaching $400.0 million and $200.0 million, respectively, in net sales of Herceptin outside of the U.S. Contract revenue from Hoffmann-La Roche, including amounts earned related to ongoing development activities after the option exercise date, totaled $66.5 million in 2003, $7.6 million in 2002 and $5.8 million in 2001. All other revenues from Roche, Hoffmann-La Roche and their affiliates, principally royalties and product sales, totaled $353.5 million in 2003, $269.9 million in 2002 and $164.1 million in 2001. In 2003, Hoffmann-La Roche's Penzberg, Germany facility became the primary site for the manufacturing of Herceptin to supply ex-U.S. territories. Our ex-U.S. sales of Herceptin to Hoffmann-La Roche were $18.8 million in 2003, $40.3 million in 2002 and $31.3 million in 2001. R&D expenses include amounts related to Roche of $37.6 million in 2003, $7.1 million in 2002, and $2.9 million in 2001.

Novartis

We understand that Novartis AG (or Novartis) holds approximately 33.3% of the outstanding voting shares of Roche Holding Ltd. As a result of this ownership, Novartis is deemed to have an indirect beneficial ownership interest under FAS 57 "Related Party Disclosures" of more than 10% of Genentech's voting stock.

In June 2003, we entered into an agreement with Novartis Opthalmics, an affiliate of Novartis AG, under which Novartis Opthalmics licensed the exclusive right to develop and market Lucentis outside of North America for the indication of age-related macular degeneration (or AMD). As part of this agreement, Novartis Opthalmics paid an upfront milestone and R&D reimbursement fee of $46.6 million and will pay 50% of Genentech's ongoing Phase III and related development expenses. Genentech is not responsible for any portion of the development and commercialization costs incurred by Novartis outside of North America, but we may receive additional payments for Novartis' achievement of certain clinical development and product approval milestones outside of North America. In addition, we will receive royalties on net sales of Lucentis products, which we will manufacture and supply to Novartis, outside of North America.

During 2000, we entered into an arrangement with Novartis, whereby Novartis was required to fund a portion of the cost of our Xolair inventory until the FDA approved the product for marketing. In June 2003, we received FDA approval to market Xolair. This amount was to be returned to Novartis upon the earlier of regulatory approval of Xolair in the U.S. or the European Union, and was recorded in other accrued liabilities in our financial statements beginning in 2000. The amount payable to Novartis was $37.8 million at December 31, 2002. In June 2003, we received FDA approval to market Xolair; in July 2003, $37.8 million of funding that had been received from Novartis was repaid. Our arrangement with Novartis allows us to record all sales and cost of sales in the U.S. Genentech and Novartis will co-develop and co-promote in the U.S. and both will separately make payments to Tanox; Genentech's will be in the form of royalties. We will pay Novartis a share of the U.S. operating profits and record it as collaboration profit sharing expense. Novartis will market the product in and record all sales and cost of sales in Europe. Genentech will receive a portion of the European operating profits or losses, which will be recorded as contract revenue. Genentech is currently manufacturing the product and receives cost plus a mark-up similar to other arrangements where we manufacture. Novartis plans to assume primary manufacturing responsibilities in the future. Collaboration profit sharing expenses were $9.9 million in 2003, $1.8 million in 2002 and not material in 2001. R&D expenses include amounts related to Novartis of $11.1 million in 2003 and $5.8 million in 2002. Such expense from Novartis in 2001 was not material.

Revenue from Novartis related to product sales and the associated cost of sales was not material in 2003 or in prior years. Contract revenue from Novartis, including amounts recognized under new licensing arrangements entered into in 2003 and amounts earned related to commercial and ongoing development activities, was $24.2 million in 2003 and $5.7 million in 2002. We had no such revenue from Novartis in 2001.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Capital Resources	2003	2002	2001
		(in millions)	
December 31:			
Cash, cash equivalents, short-term investments and long-term marketable debt and equity securities	$ 2,934.7	$1,601.9	$2,864.9
Working capital	1,883.8	1,436.1	1,557.6
Current ratio	3.2:1	3.2:1	3.3:1
Year Ended December 31:			
Cash provided by (used in):			
Operating activities	1,236.9	587.7	480.6
Investing activities	(1,398.4)	(6.5)	(704.0)
Financing activities	325.5	(768.3)	67.2
Capital expenditures (included in investing activities above)	(322.0)	(322.8)	(213.4)

We use cash generated from operations, income from investments and proceeds from stock issuances to fund operations, purchase marketable securities, make capital and equity investments, make stock repurchases, and in 2002, to redeem our debentures which matured in the first quarter of 2002. In addition, in 2002, we pledged $630.0 million in cash and investments to secure the surety bond related to the City of Hope National Medical Center (or COH) judgment. (See the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding the COH litigation and related surety bond.)

Cash flows from operations can vary significantly due to various factors including changes in accounts receivable and deferred revenues related to large opt-in and new arrangements with collaborators. The average collection period of our accounts receivable as measured in days sales outstanding (or DSO) can vary and is dependent on various factors, including the type of revenue (i.e., product sales, royalties, or contract revenue) and the payment terms related to those revenues and whether the related revenue was recorded at the beginning or at the end of a period.

Under a stock repurchase program approved by our Board of Directors on December 5, 2003, Genentech is authorized to repurchase up to $1 billion of its common stock through December 31, 2004. In this plan, as in previous stock repurchase plans, purchases may be made in the open market or in privately negotiated transactions from time to time at management's discretion. Genentech also may engage in transactions in other Genentech securities in conjunction with the repurchase program, including certain derivative securities. Genentech intends to use the repurchased stock to offset dilution caused by the issuance of shares in connection with Genentech's employee stock plans. Although there are currently no specific plans for the shares that may be purchased under the program, our goals for the program are (i) to make prudent investments of our cash resources; (ii) to allow for an effective mechanism to provide stock for our employee stock plans; and (iii) to address provisions of our affiliation agreement with Roche relating to maintaining Roche's minimum ownership percentage. Under a previous stock repurchase program approved by our Board of Directors, Genentech was authorized to repurchase up to $1 billion of our common stock through the period ended June 30, 2003.

Our stock repurchases under the above plans are summarized below *(in thousands)*.

	TOTAL		2003		2002		2001	
	Shares	Amounts	Shares	Amounts	Shares	Amounts	Shares	Amounts
Approved by Board pre-program	800	$ 34,034	—	$ —	—	$ —	800	$34,034
Repurchase program expired June 30, 2003	23,775	893,696	5,434	195,274	18,241	692,752	100	5,670
Repurchase program expiring December 31, 2004	71	6,071	71	6,071	—	—	—	—
Total repurchases	24,646	$933,801	5,505	$201,345	18,241	$692,752	900	$39,704

The par value method of accounting is used for common stock repurchases. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital with the amounts in excess of the estimated original sales price charged to accumulated deficit.

Capital expenditures in 2003 included continuing construction of and improvements to manufacturing and R&D facilities and new spending on construction of and improvements to office buildings in South San Francisco. Capital expenditures in 2002 consisted primarily of the purchase of land and the construction of and improvements to manufacturing and R&D facilities. In 2004, we expect to spend approximately $800.0 million on property, plant and equipment. The increase over 2003 will primarily support our expected future manufacturing capacity needs, increases in property, equipment and information systems related purchases, and provide for synthetic lease repayments.

In March 2002, we redeemed in cash $149.7 million of convertible subordinated debentures, classified as short-term debt, with interest payable at 5%.

Our total cash, cash equivalents, short-term investments and marketable securities are expected to decline over the next several years due to cash requirements for capital expenditures, share repurchases under our stock repurchase program, synthetic lease repayments and working capital. These funds, together with funds provided by operations and leasing arrangements, will be sufficient to meet our foreseeable future operating cash requirements. In addition, we believe we could access additional funds from the debt and, under certain circumstances, capital markets. See also "Our Affiliation Agreement with Roche Could Adversely Affect Our Cash Position" below for factors that could negatively affect our cash position and the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K.

OFF-BALANCE SHEET ARRANGEMENTS

We have certain contractual arrangements that create risk for the company and are not recognized in our consolidated balance sheet. Discussed below are those off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operation, liquidity, capital expenditures or capital resources.

Leases

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance and minimum lease payments. Some of our leases have options to renew. Four of our operating leases are commonly referred to as "synthetic leases." Prior to the issuance of FIN 46, synthetic leases represented a form of off-balance sheet financing under which they were treated as operating leases for accounting purposes and as financing leases for tax purposes. Under FIN 46, each synthetic lease is evaluated to determine if it qualifies as a VIE and whether Genentech is the primary beneficiary under which it would be required to consolidate the VIE.

Under our synthetic lease structures, an unrelated third-party funds 100% of the costs of the acquisition and/or construction of the property and leases the asset to us, as the lessee, and at least 3% of the third-party funds represent at-risk equity. In addition, under our synthetic lease structures, upon termination or expiration, at our option, we must either purchase the property from the lessor at a predetermined amount that does not constitute a purchase at less than fair market value, sell the real property to a third-party, or renew the lease arrangement. If the property is sold to a third-party at an amount less than the amount financed by the lessor, we have agreed under residual value guarantees to pay the lessor up to an agreed upon percentage of the amount financed by the lessor.

The most significant of our synthetic leases relates to our manufacturing facility located in Vacaville, California. In November 2001, we completed a synthetic lease transaction for this facility, which had previously been leased to us under a predecessor synthetic lease. This new synthetic lease is structured differently from our other synthetic leases. As the lessee, we lease the property from an unrelated special purpose trust (owner/lessor) under an operating lease agreement for five years ending November 2006. Third-party financing is provided in the form of a 3% at-risk equity participation from investors and 97% debt commitment. Investors' equity contributions were equal to or greater than 3% of the fair value of the property at the lease's inception and are required to remain so for the term of the lease. A bankruptcy-remote, special purpose corporation (or SPC) was formed to fund the debt portion through the issuance of commercial paper notes. The SPC lends the proceeds from the commercial paper to the owner/lessor, who issues promissory notes to the SPC. The SPC loans mature in November 2006. The SPC promissory notes are supported by a credit facility provided by financing institutions and draws are generally available under that credit facility to repay the SPC's commercial paper. The collateral for the SPC loans includes the leased property, and an interest in the residual value guarantee provided by us. The creditors of the SPC do not have recourse to the general credit of Genentech. As the lessee, at any time during the lease term, we have the option to purchase the property at an amount that does not constitute a purchase at less than fair market value.

Under FIN 46, we determined that the entity from which we lease the Vacaville facility qualified as a VIE and that we are the primary beneficiary of this VIE as we absorb the majority of the entity's expected losses. Upon adoption of the provisions of FIN 46 on July 1, 2003, we consolidated the entity. See above in the "Critical Accounting Policies — Changes in Accounting Principles" section for further information on our adoption of FIN 46.

Our three remaining leases were entered into with BNP Paribas Leasing Corporation (or BNP), who leases directly to us various buildings that we occupy in South San Francisco, California. Under certain of these leases, we are required to maintain cash collateral of $56.6 million, which we have included in our consolidated balance sheets as restricted cash and investments. We have evaluated our accounting for these leases under the provisions of FIN 46, and we determined that, as of July 1, 2003, we are not required to consolidate either the leasing entity or the specific assets that we lease under the BNP leases.

Under all the synthetic leases, Genentech, as the lessee, is also required to maintain certain pre-defined financial ratios and is limited to the amount of debt it can assume. In addition, no Genentech officer or employee has any financial interest with regard to these synthetic lease arrangements or with any of the special purpose entities used in these arrangements. In the event of a default, the maximum amount payable under the residual value guarantee would equal 100% of the amount financed by the lessor, and our obligation to purchase the leased properties or pay the related residual value guarantees could be accelerated. We believed at the inception of the leases and continue to believe that the occurrence of any event of default that could trigger our purchase obligation is remote.

See the contractual obligations table below for our future minimum lease payments under all leases, exclusive of the residual value guarantees, executory costs and sublease income, at December 31, 2003. These minimum lease payments were computed based on interest rates current at that time, which are subject to fluctuation in certain market-based interest rates.

The following summarizes the approximate initial fair values of the facilities at the inception of the related leases, lease terms and residual value guarantee amounts for each of our synthetic leases *(in millions)*:

	Approximate Initial Fair Value of Leased Property	Lease Expiration	Maximum Residual Value Guarantee
Vacaville lease	$425.0	11/2006	$371.8
South San Francisco lease 1	56.6	07/2004	48.1
South San Francisco lease 2	160.0	06/2007	136.0
South San Francisco lease 3	25.0	01/2004	21.3
Total	$666.6		$577.2

We believe that there have been no impairments in the fair value or use of the properties that we lease under synthetic leases wherein we believe that we would be required to pay amounts under any of the residual value guarantees. We will continue to assess the fair values of the underlying properties and the use of the properties for impairment at least annually.

The maximum exposure to loss on our synthetic leases includes (i) residual value guarantee payments as shown above, (ii) certain tax indemnifications in the event the third-parties are obligated for certain federal, state or local taxes as a result of their participation in the transaction, and (iii) indemnification for various losses, costs and expenses incurred by the third-party participants as a result of their ownership of the leased property or participation in the transaction, and as a result of the environmental condition of the property. The additional taxes, losses and expenses as described in (ii) and (iii) are contingent upon the existence of certain conditions and, therefore, would not be quantifiable at this time. However, we do not expect these additional taxes, losses

and expenses to be material. In the case of South San Francisco lease 1, we have pledged cash collateral of $56.6 million as a source of payment for Genentech's obligation for the residual value guarantee payments and other amounts we owe under the lease.

Commitments

In December 2003, we entered into a non-exclusive long-term manufacturing agreement with Lonza Biologics, a subsidiary of Lonza Group Ltd, under which Lonza will manufacture commercial quantities of Rituxan for us at Lonza's production facility in Portsmouth, New Hampshire. We may be obligated to make milestone payments to Lonza subject to Lonza's achievement of a series of factory preparation and process validation milestones, as well as receipt of FDA approval for the manufacturing of Rituxan bulk drug at the Lonza facility; the amounts of such payments cannot be estimated at this time. Following FDA approval at the Lonza facility, it is expected that commercial production would begin in 2005.

We have an agreement with Serono S.A.; our agreement, in addition to granting marketing rights to Serono in specific areas of the world, includes an arrangement to collaborate on co-developing additional indications of Raptiva and to share certain global development costs. We also have a supply agreement with Serono, under which we may have a loss exposure up to a maximum of $10.0 million.

We have a manufacturing agreement with Immunex Corporation, a wholly-owned subsidiary of Amgen, to provide Immunex with additional manufacturing capacity for ENBREL® (etanercept) at Genentech's manufacturing facility in South San Francisco, California. As part of the agreement, we are responsible for facility modifications needed to manufacture ENBREL, including the internal labor costs and costs of certain raw materials for development runs. The facility modification and services costs, which include engineering and equipment costs, are reimbursable by Immunex. However, if certain milestones are not met, we are required to reimburse Immunex for up to 45% of the facility modification and services costs. Costs associated with development runs are reflected in R&D expense as incurred. Shipment of the product, including pre-approval product, to Immunex would be recorded as product sales based on an agreed upon price with the associated costs reflected in cost of sales. In the fourth quarter of 2003, we determined that certain milestones, including obtaining FDA approval for the manufacturing process, would likely not be met in the pre-agreed upon timeframe. As a result, certain equipment paid for by us related to ENBREL manufacturing will not qualify for reimbursement by Immunex. Certain ENBREL-related equipment in our consolidated balance sheet will be depreciated over the estimated useful life of the equipment and certain of it will be depreciated over the term of the supply arrangement.

Contractual Obligations

Payments due under contractual obligations at December 31, 2003 mature as follows:

		Payments due by period (in millions)			
Contractual Obligations	**Total**	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**
Operating lease obligations[1]					
Vacaville synthetic lease[2]	$ 18.0	$ 6.2	$ 11.8	$ —	$ —
South San Francisco synthetic leases	6.4	2.7	3.7	—	—
Other leases	54.9	6.5	12.7	11.6	24.1
Purchase obligations[3]	73.4	62.9	10.5	—	—
Long-term debt[2]	412.3	—	412.3	—	—
Other long-term liabilities[2] [4]	649.3	—	649.3	—	—
Total	$1,214.3	$78.3	$1,100.3	$11.6	$24.1

(1) See further discussion of our operating leases above in "Leases."

(2) Upon adoption of FIN 46, we consolidated the entity from which we lease our manufacturing facility located in Vacaville, California. We also consolidated the entity's debt of $412.3 million and noncontrolling interests of $12.7 million, which amounts are included in long-term debt and other long-term liabilities, respectively, at December 31, 2003.

(3) Purchase obligations include commitments related to capital expenditures, clinical development, collaborations, manufacturing and research operations and other significant purchase commitments

(4) Other long-term liabilities include our deferred tax liabilities, litigation liabilities, noncontrolling interests in a VIE and other similar items which are reflected on our balance sheet under GAAP. We have excluded our deferred revenues as they have no effect on our future liquidity.

STOCK OPTIONS

Option Program Description

Our stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our program primarily consists of our amended and restated 1999 Stock Plan (the "Plan"), a broad-based plan under which stock options are granted to employees, directors and other service providers. Substantially all of our employees participate in our stock option program. In the past, we granted options under our amended and restated 1996 Stock Option/Stock Incentive Plan, our amended and restated 1994 Stock Option Plan and our amended and restated 1990 Stock Option/Stock Incentive Plan. Although we no longer grant options under these plans, exercisable options granted under these plans are still outstanding.

We also have a stock repurchase program in place and one purpose of the program is to manage the dilutive effect generated by the exercise of stock options. All stock option grants are made after a review by, and with the approval of, the Compensation Committee of the Board of Directors. See "The Compensation Committee Report" appearing in our Proxy Statement for further information concerning the policies and procedures of the Compensation Committee regarding the use of stock options.

General Option Information

Summary of Option Activity

(Shares in thousands)

		Options Outstanding	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
December 31, 2001	14,509	46,640	$41.06
Grants	(12,655)	12,655	28.98
Exercises	—	(1,673)	23.43
Cancellations[1]	2,195	(2,203)	53.16
Additional shares reserved	—	—	—
December 31, 2002	4,049	55,419	38.37
Grants	(10,890)	10,890	81.09
Exercises	—	(16,039)	68.27
Cancellations[1]	2,207	(2,207)	47.59
Additional shares reserved	25,000	—	—
December 31, 2003	20,366	48,063	$50.36

(1) We currently only grant shares under our amended and restated 1999 Stock Plan. Cancellations from options granted under previous plans are not added back to the shares reserved for issuance under the 1999 Stock Plan.

In-the-Money and Out-of-the-Money Option Information

(Shares in thousands)

As of December 31, 2003	Exercisable		Unexercisable		Total	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
In-the-Money	23,786	$42.81	24,256	$57.73	48,042	$50.34
Out-of-the-Money(1)	18	95.66	3	95.66	21	95.66
Total Options Outstanding	23,804		24,259		48,063	

(1) Out-of-the-money options are those options with an exercise price equal to or greater than the fair market value of Genentech Common Stock, $93.57, at the close of business on December 31, 2003.

Distribution and Dilutive Effect of Options

Employee and Executive Officer Option Grants

	2003	2002	2001
Net grants during the year as % of outstanding shares	1.69%	1.98%	1.64%
Grants to Named Executive Officers* during the period as % of outstanding shares	0.18%	0.25%	0.22%
Grants to Named Executive Officers during the year as % of total options granted	8.54%	10.27%	10.52%

* "Named Executive Officers" refers to our CEO and our four other most highly compensated executive officers as defined under Item 402(a)(3) of Regulation S-K of the federal securities laws.

Equity Compensation Plan Information

Our stockholders have approved all of our equity compensation plans under which options are outstanding.

FORWARD-LOOKING INFORMATION AND CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This Form 10-K contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of Genentech, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, royalties, contract revenues, expenses, net income and earnings per share.

The Successful Development of Biotherapeutics Is Highly Uncertain and Requires Significant Expenditures

Successful development of biotherapeutics is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including:

- Preclinical and clinical trial results that may show the product to be less effective than desired (e.g., the trial failed to meet its primary objectives) or to have harmful or problematic side effects.
- Failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, extended length of time to achieve study endpoints, additional time requirements for data analysis or Biologics License Application (or BLA) preparation, discussions with the U.S. Food and Drug Administration (or FDA), an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues.
- Manufacturing costs, pricing or reimbursement issues, or other factors that make the product uneconomical.
- The proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict.

Factors affecting our research and development (or R&D) expenses include, but are not limited to:

- The number of and the outcome of clinical trials currently being conducted by us and/or our collaborators. For example, our R&D expenses may increase based on the number of late-stage clinical trials being conducted by us and/or our collaborators.
- The number of products entering into development from late-stage research. For example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external candidate will be available on terms acceptable to us. In the past, some promising candidates did not yield sufficiently positive preclinical results to meet our stringent development criteria.
- Hoffmann-La Roche's decisions whether to exercise its options to develop and sell our future products in non-U.S. markets and the timing and amount of any related development cost reimbursements.
- In-licensing activities, including the timing and amount of related development funding or milestone payments. For example, we may enter into agreements requiring us to pay a significant upfront fee for the purchase of in-process research and development (or IPR&D), which we may record as an R&D expense.
- As part of our strategy, we invest in R&D. R&D as a percentage of revenues can fluctuate with the changes in future levels of revenue. Lower revenues can lead to more limited spending on R&D efforts.
- Future levels of revenue.

We May Be Unable to Obtain or Maintain Regulatory Approvals for Our Products

The biotechnology and pharmaceutical industries are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA's requirements covering R&D, testing, manufacturing, quality control, labeling and promotion of drugs for human use. A biotherapeutic cannot be marketed in the United States until it has been approved by the FDA, and then can only be marketed for the indications and claims approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application (or NDA) or a BLA, are substantial and can require a number of years. In addition, after any of our products receive regulatory approval, they remain subject to ongoing FDA regulation, including, for example, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians and a product recall.

We cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for any of the products we are developing or manufacturing or that we can maintain necessary regulatory approvals for our existing products, and all of the following could have a material adverse effect on our business:

- Significant delays in obtaining or failing to obtain required approvals as described in "The Successful Development of Biotherapeutics is Highly Uncertain and Requires Significant Expenditures" above.
- Loss of, or changes to, previously obtained approvals.
- Failure to comply with existing or future regulatory requirements.
- Changes to manufacturing processes, manufacturing process standards or Good Manufacturing Practices following approval or changing interpretations of these factors.

Moreover, it is possible that the current regulatory framework could change or additional regulations could arise at any stage during our product development or marketing, which may affect our ability to obtain or maintain approval of our products.

Difficulties or Delays in Product Manufacturing Could Harm Our Business

We currently produce all of our products at our manufacturing facilities located in South San Francisco, California and Vacaville, California or through various contract-manufacturing arrangements. Problems with any of our or our contractors' manufacturing processes could result in failure to produce adequate product supplies or product defects, which could require us to delay shipment of products, recall products previously shipped or be unable to supply products at all.

In addition, any prolonged interruption in the operations of our or our contractors' manufacturing facilities could result in cancellations of shipments, loss of product in the process of being manufactured, or a shortfall of available product inventory. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials used for manufacture of our products, equipment malfunctions or failures, damage to a facility due to natural disasters, including earthquakes as our South San Francisco and Vacaville facilities are located in an area where earthquakes could occur, changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes, action by the FDA or by the Company that results in the halting or slowdown of production of one or more of our products due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because our manufacturing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our and our contractors' manufacturing and supply of existing or new products could increase our costs, cause us to lose revenue or market share and damage our reputation.

We may also experience insufficient available capacity to manufacture or have manufactured for us existing or new products which could cause shortfalls of available product inventory and an inability to supply market

demand of one or more of our products for either a short period of time or an extended period of time. Alternatively, we may have an excess of available capacity which could lead to an idling of a portion of our manufacturing facilities and incurring idle plant charges, resulting in an increase in our costs of sales.

We May Be Unable to Manufacture Certain of Our Products if There is BSE Contamination of Our Bovine Raw Material

Most biotechnology companies, including Genentech, have historically used bovine source raw materials to support cell growth in cell production processes. Bovine source raw materials from within or outside the United States are increasingly subject to greater public and regulatory scrutiny because of the perceived risk of contamination with bovine spongiform encephalopathy (or BSE). We have taken, and are continuing to take, precautions to minimize the risk of BSE contamination in our bovine source raw materials. We closely document the use of bovine source raw materials in our processes, take stringent measures to use the purest ingredients available and are working towards transitioning our processes to remove bovine source raw materials from final formulations. We are also in compliance with applicable U.S. and European guidelines on the handling and use of bovine source raw materials. Because of these efforts as well as those of the FDA, we believe that the risk of BSE contamination in our source materials is very low. However, should BSE contamination occur during the manufacture of any of our products that require the use of bovine source raw materials, namely Rituxan, it would negatively impact our ability to manufacture those products for an indefinite period of time (or at least until an alternative process is approved), and could result in a material adverse effect on our product sales, financial condition and results of operations.

Decreases in Third Party Reimbursement Rates May Affect Our Product Sales

The Medicare Prescription Drug Improvement and Modernization Act, enacted in December 2003, provides for, among other things, a reduction in the Medicare reimbursement rates for many drugs, including our oncology products, possibly offset to some extent by increased physician payment rates for drug administration services related to certain of our oncology products. The Congressional rationale for this legislation was that (1) the payment for drugs by the Medicare program should more closely reflect the acquisition costs for those drugs, and (2) the reimbursement for the service codes associated with the administration of drugs should be increased to better reflect practice expense costs associated with those services. The Medicare Act as well as other changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for our products may reduce or eliminate reimbursement of our products' costs to physicians. Decreases in third party reimbursement for our products, namely Rituxan and especially with respect to 2004, could reduce physician usage of the product and have a material adverse effect on our product sales, results of operations and financial condition. We are unable to predict what impact the Medicare Act or other future regulation, if any, relating to third-party reimbursement, will have on sales of Rituxan or our oncology or other products.

Protecting Our Proprietary Rights Is Difficult and Costly

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in these companies' patents. Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material patent litigation, such as the matters discussed in the "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or commercializing the product in dispute.

The presence of patents or other proprietary rights belonging to other parties may lead to our termination of the R&D of a particular product.

We believe that we have strong patent protection or the potential for strong patent protection for a number of our products that generate sales and royalty revenue or that we are developing. However, it is for the courts in the U.S. and in other jurisdictions ultimately to determine the strength of that patent protection.

The Outcome of, and Costs Relating to, Pending Litigation or Other Legal Actions are Uncertain

Litigation to which we are currently or have been subjected relates to, among other things, our patent and other intellectual property rights, licensing arrangements with other persons, product liability and financing activities. We cannot predict with certainty the eventual outcome of pending litigation, which may include an injunction against the manufacture or sale of a product or potential product or a significant jury verdict or punitive damages award, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable. Furthermore, we may have to incur substantial expense in defending these lawsuits.

Our activities relating to the sale and marketing of our products are subject to regulation under the Federal Food, Drug and Cosmetic Act and other federal statutes, including those relating to government program fraud and abuse. We believe our sales and marketing activities are in compliance with these laws. Violations of these laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to bring charges against or convict us of violating these laws, there could be a material adverse effect on our business, including our stock price.

We May Be Unable to Retain Skilled Personnel and Maintain Key Relationships

The success of our business depends, in large part, on our continued ability to attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, and on our ability to develop and maintain important relationships with leading research institutions and key distributors. Competition for these types of personnel and relationships is intense.

Roche has the right to maintain its percentage ownership interest in our common stock. Our affiliation agreement with Roche provides that, among other things, we will establish a stock repurchase program designed to maintain Roche's percentage ownership in our common stock if we issue or sell any shares. This could have an effect on the number of shares we are able to grant under our stock option plans. We therefore cannot assure you that we will be able to attract or retain skilled personnel or maintain key relationships.

We Face Competition

We face competition in five of our therapeutic markets. First, in the thrombolytic market, Activase and TNKase have lost market share and could lose additional market share to Centocor's Retavase® (approved in 1996 for the treatment of acute myocardial infarction) and to the use of mechanical reperfusion therapies to treat acute myocardial infarction; the resulting adverse effect on sales has been and could continue to be material. We expect that the use of mechanical reperfusion in lieu of thrombolytic therapy for the treatment of acute myocardial infarction will continue to grow. In addition, we face potential competition in the catheter clearance market from the reintroduction of Abbott Laboratories' Abbokinase® (urokinase) in October 2002.

Second, in the growth hormone market, we face competition from other companies currently selling growth hormone products and delivery devices. As a result of that competition, we have experienced a loss in market share in the past. Competitors have also received approval to market their existing growth hormone products for additional indications. As a result of this competition, market share of our growth hormone products may decline. In addition, we have certain patents related to the production of growth hormone that have expired and as a consequence those patents no longer exclude others from making growth hormone using the processes claimed by those patents. Any competitive entry as a result of expiration of our patents may cause further decline in our market share.

Third, in the non-Hodgkin's lymphoma market, Corixa Corporation received FDA approval in June 2003, for Bexxar™ (tositumomab and iodine I 131 tositumomab), which may potentially compete with our product Rituxan. Biogen Idec Inc. (or Biogen Idec), formerly known as IDEC Pharmaceuticals Corporation, received marketing approval from the FDA and began commercial shipments in late March 2002 for Zevalin™ (ibritumomab tiuxetan), a product that could also potentially compete with Rituxan. Both Bexxar and Zevalin are radiolabeled molecules while Rituxan is not. We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphoma in development.

Fourth, Raptiva competes with established therapies for moderate-to-severe psoriasis including oral systemics such as methotrexate and cyclosporin, as well as ultraviolet light therapies. In addition, Raptiva competes with Biogen Idec's biologic therapy Amevive® (alefacept), approved by the FDA in January 2003 for the treatment of moderate-to-severe psoriasis. Raptiva also competes with drugs approved for other indications that are used in psoriasis. Additional biologic therapies are expected to enter the psoriasis market in the next several years. ENBREL® (etanercept), marketed by Amgen and Wyeth in the U.S., is already approved for psoriatic arthritis, a condition associated with psoriasis. In 2003, Amgen announced positive Phase III trial results using ENBREL for moderate-to-severe plaque psoriasis, and subsequently announced that ENBREL was filed for FDA approval to treat the condition. Other products are known to be in development for the psoriasis market.

Finally, Avastin may compete with Oxaliplatin. Avastin has been approved for use as first-line therapy for metastatic colorectal cancer patients in combination with intravenous 5-fluorouracil ("5-FU")-based chemotherapy. In the Avastin pivotal trial, first-line patients were treated with an irinotecan-based regimen, 5-FU/Leucovorin and CPT-11 (or "the Saltz Regimen"). In another Phase II trial, Avastin was found to provide benefit for first line patients when used in combination with 5-FU/Leucovorin alone. These regimens represent approximately 40% of all treatments used in the first-line setting. However, the use of these regimens is likely to decline as more physicians adopt Oxaliplatin-based regimens in the first-line setting. Avastin is currently being studied in combination with 5-FU/ Leucovorin and Oxaliplatin (the "FOLFOX Regimen") in patients with relapsed, metastatic colorectal cancer in a large randomized study through the Eastern Cooperative Oncology Group (the "E3200 Trial"). If the results from the E3200 Trial are positive for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin or show a similar magnitude of benefit as previous colorectal cancer studies with Avastin, use of Avastin may increase as physicians increase their use of Avastin in combination with Oxaliplatin-based regimens in the relapsed, and also the first-line setting. However, if the results of the E3200 Trial are negative for the combination of Avastin and 5-FU/Leucovorin and Oxaliplatin, potential sales of Avastin may be materially adversely affected as physicians may limit their use of Avastin to irinotecan-based regimens. Physicians may also restrict their use of Avastin to first-line patients only.

Other Factors Could Affect Our Product Sales

Other factors that could affect our product sales include, but are not limited to:

- The timing of FDA approval, if any, of competitive products.
- Our pricing decisions, including a decision to increase or decrease the price of a product, and the pricing decisions of our competitors.
- Government and third-party payer reimbursement and coverage decisions that affect the utilization of our products and competing products.
- Negative data from new clinical studies could cause the utilization and sales of our products to decrease.
- The degree of patent protection afforded our products by patents granted to us and by the outcome of litigation involving our patents.
- The outcome of litigation involving patents of other companies concerning our products or processes related to production and formulation of those products or uses of those products. For example, as described in "Leases, Commitments and Contingencies" note in the Notes to Consolidated Financial